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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

05/29/2008

Stephen M Haracz
Bryan Cave
1290 Avenue of the Americas
New York, NY 10104

EXAMINER

CHOWDHURY, IQBAL HOSSAIN

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 05/29/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,844	02/03/2006	Tatsuo Hoshino	21425 US C038435/0185658	2034
TITLE OF INVENTION: DNA ENCODING FLAVIN-ADENINE-DINUCLEOTIDE-DEPENDENT-D-ERYTHRONATE-4-PHOSPHATE-DE-HYDROGENASE, PRODUCTION OF VITAMIN B6 PDXR, AND MICROBIAL				

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	\$0	\$1740	08/29/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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05/29/2008

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,844	02/03/2006	Tatsuo Hoshino	21425 US	2034
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APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	\$0	\$1740	08/29/2008

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHOWDHURY, IQBAL HOSSAIN	1652	435-471000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). <input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. <input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.	2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____ (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____ 3 _____
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3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted: <input type="checkbox"/> Issue Fee <input type="checkbox"/> Publication Fee (No small entity discount permitted) <input type="checkbox"/> Advance Order - # of Copies _____	4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above) <input type="checkbox"/> A check is enclosed. <input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached. <input type="checkbox"/> The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).
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5. Change in Entity Status (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____
 Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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			1652	
DATE MAILED: 05/29/2008				

Stephen M Haracz
Bryan Cave
1290 Avenue of the Americas
New York, NY 10104

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.

10/528,844

Applicant(s)

HOSHINO ET AL.

Examiner

Art Unit

IQBAL H. CHOWDHURY

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/17/2008.
2. ☒ The allowed claim(s) is/are 1-3.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date ____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other ____. |

DETAILED ACTION

Application Status

Claims 1-3 are currently pending in this application.

In response to a previous Office action, a final action (mailed on October 12, 2007), Applicants filed an amendment on April 17, 2008, and amending claim 1 is acknowledged.

Claims 1-3 are under consideration and are present for examination.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jihong Zang, the representative of the instant application on May 21, 2008.

Please replace the abstract with the abstract found on the attached sheet. **Amend claims as follows:**

Replace "Claim 1" with "Claim 1. A process for the biological production of vitamin B6 which comprises cultivating a host cell transformed or transfected by an isolated DNA or by a vector or plasmid comprising the isolated DNA under conditions conducive to the production of vitamin B6, and recovering vitamin B6 from the culture, wherein the host cell is selected from *Sinorhizobium* or *Escherichia* and wherein the isolated DNA comprises a

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nucleotide sequence encoding PdxR, which is a flavin adenine dinucleotide-dependent D-erythronate 4-phosphate dehydrogenase, selected from the group consisting of:

(a) a DNA sequence of ~~identified by SEQ ID NO:1 or the complementary strand thereof;~~

~~(b) a DNA sequence which hybridizes under stringent hybridization and stringent washing conditions to the DNA sequence complementary to the DNA sequence defined in (a), and encodes a polypeptide having the activity of flavin adenine dinucleotide dependent D-erythronate 4-phosphate dehydrogenase, wherein the stringent hybridization conditions comprise hybridization in 2XSSC and 0.5% sodium dodecyl sulfate (SDS) at 45°C for 1 hour and wherein the stringent washing conditions comprise washing in 0.1X SSC and 0.5% SDS at 60°C for 1 hour;~~

~~(c) a DNA sequence encoding a polypeptide having the amino acid sequence encoded by the DNA sequence of (a), or (b), or (d);~~

(b) ~~(d)~~ a DNA sequence encoding a polypeptide which is at least ~~[[80%]]~~ 95% identical to a ~~DNA encoding a polypeptide which comprises the amino acid sequence of SEQ ID NO: 2, and~~ encodes a polypeptide having the activity of flavin adenine dinucleotide-dependent D-erythronate 4-phosphate dehydrogenase; and

(c) ~~(e)~~ a DNA sequence encoding a polypeptide which comprises the amino acid sequence ~~which is at least 80% identical to the amino acid sequence of SEQ ID NO: 2, and~~ encodes a polypeptide having the activity of flavin adenine dinucleotide-dependent D-erythronate 4-phosphate dehydrogenase.

Claim 2, line 2-3, replace “(a) to (e)” with “(a) to (c)”.

Claim 2, line 3-4, replace “*Sinorhizobium meliloti* or *Escherichia coli*” with “*Sinorhizobium meliloti* or *Escherichia coli*”.

Claim 3, line 2, replace “*Sinorhizobium*” with “*Sinorhizobium*”.

Allowable Subject Matter

Claims 1-3 are allowed.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The applicant has claimed a process for the biological production of vitamin B6 which comprises cultivating a host cell transformed or transfected by an isolated DNA or a vector comprising said DNA of SEQ ID NO: 1 encoding a protein of SEQ ID NO: 2 having flavin dinucleotide-dependent D-erythronate 4-phosphonate dehydrogenase activity. The prior art does not teach an isolated protein having an amino acid sequence shown in SEQ ID NO: 2 encoded by nucleic acid molecule of SEQ ID NO: 1 and process for producing vitamin B6.

The closest prior arts are Capela et al. (GenBank Accession No. AL591783 for nucleic acid, created 8/1/2001, and GenBank Accession No. Q92SG4, for protein, created 12/1/2001), and Yocum et al. (US PGPUB 2005/0164335 A1, publication 7/28/2005, claim priority of 60/367,863 of 3/25/2002 and 60/368,618 of 3/29/2002). Capela et al. (UniProt) teach a protein sequence based on genome sequence of *S. meliloti* predicted to be a putative oxidoreductase type protein and Yocum et al. teach a process for producing vitamin B6 by using a gene which is 10% identical to SEQ ID NO: 1. Therefore, one of ordinary skilled artisan would not be expected to

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use the encoding oxidoreductase protein of Capela et al. to combine with the method of producing vitamin B6 as taught by Yocum et al. at the time of invention was made to produce vitamin B6 by using said oxidoreductase gene. The sequence identity data also suggest that there were no sequence having significant sequence identity to SEQ ID NO: 2 to suggest or motivate to use oxidoreductase type of gene encoding protein could be used for vitamin B6 biosynthesis.

A standard search did not produce any prior art that suggests or teaches the claimed invention.

The claimed invention is novel and nonobvious over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, Ph.D. whose telephone number is (571) 272-8137. The examiner can normally be reached on Monday-Friday from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed, can be reached at (571) 272-0934.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal Chowdhury, PhD, Patent Examiner
Art Unit 1652 (Recombinant Enzymes)
US Patent and Trademark Office
Rm. REM 2B69, Mail Box. 2C70
Ph. (571)-272-8137, Fax. (571)-273-8137
/I. H. C./

Examiner, Art Unit 1652

/Rebecca E. Prouty/
Primary Examiner,
Art Unit 1652

Abstract

The present invention relates to a DNA encoding a novel flavin adenine dinucleotide (FAD)-dependent D-erythronate 4-phosphate (EN4P) dehydrogenase originated from *Sinorhizobium meliloti*, which is involved in vitamin B6 biosynthesis, and a recombinant microorganism transformed with a vector having the DNA. It also relates to a process for production of vitamin B6 by using the recombinant microorganism. "Vitamin B6" as used in this invention includes pyridoxol (PN), pyridoxal and pyridoxamine. Vitamin B6 is a vitamin indispensable to human beings or other animals, and is used as a raw material of medicines or as feed additives.